



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,385	08/24/2001	Scott Levine		3458

7590 05/20/2005
Scott Levine MD
7350 Sandlake Commons Blvd., Ste 2215
Orlando, FL 32819

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,385

Applicant(s)

LEVINE, SCOTT

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-74 is/are pending in the application.
4a) Of the above claim(s) 42-63 is/are withdrawn from consideration.
5) ☒ Claim(s) 64 is/are allowed.
6) ☒ Claim(s) 24-31, 34-37, 39-41, 65, 67-70 and 72-74 is/are rejected.
7) ☒ Claim(s) 32, 33, 38, 66 and 71 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1623

DETAILED ACTION

The Amendment filed September 28, 2004 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 26-30, 34, 36-41, and 64 have been amended.

Claims 65-74 have been added

Claims 42-63 have been withdrawn.

Claims 1-23 have been canceled.

Remarks drawn to rejections of Office Action mailed June 1, 2004 include:

112 1st paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(b) rejections: which has been maintained for reasons of record.

An action on the merits of claims 24-41 and 64-74 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1623

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-41 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/704,308. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are optionally encompass treating diet-related cancers by administering the same composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 34, 41, 69, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 34, 41, 69, and 74, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The rejection of claims 24-27, 29-31, and 34-36 under 35 U.S.C. 102(b) as being anticipated by Ringe et al. (US Patent 5,026,689), is maintained for reasons of record.

Claim 24 is drawn to a composition comprising at least 7 grams of fiber per serving and comprising a mixture of guar, oat, psyllium, and a flavoring agent. Claim 25 provides that the mixture comprises 1-15g of guar, 1-15g of oat, and 0.5-10g of psyllium. Claim 26 provides that there is an additional agent incorporated to create a liquid, semisolid, or solid product. Claim 27 provides that there is an additional fiber in the composition. Claim 29 provides that there is an additional agent incorporated to create a solid or semisolid of puddings, snack bars, or wafers. Claim 30 provides there is a sweetener. Claim 31 provides there is an additional agent, which is selected from coloring agents, preservatives, thickening agents, thinning agents, or emulsifiers. Claim 34 provides vitamins are optionally added, claim 35 provides that carbohydrates are optionally added, and claim 36 provides that a sweetener is optionally added.

Ringe et al. disclose a composition comprising oat, psyllium, and guar, as well as a malt syrup (flavorant) wherein the fiber content is disclosed as being 7.2 g/oz (example 3) and 7.7 g/oz (example 4). Moreover, Ringe disclose that a dosage of 0.8-1.5 g/kg can be eaten 1-3 times daily (see column 3, lines 1-7). It is noted that an 80 kg person (about 150 lbs) would be required to ingest about 3 oz of product based on a 1 g/kg dosage (1 g/kg = 80 g/80 kg: 80g is about 3 oz). Moreover, the percentages by weight of the compositions of examples 3 and 4 are seen to be correlative to the weight in grams as set forth in claim 25 of the instant application. The product of Ringe et al. is disclosed as being a cereal (solid). Ringe et al. additionally disclose adding

Art Unit: 1623

wheat bran to their composition (an insoluble fiber). Ringe et al. disclose that their composition can be fabricated into a variety of common cereal forms including shreds, biscuits, flakes, or any form, shape or size (column 7, lines 65-69). Moreover, Ringe et al. disclose the addition of sugar (a sweetener/carbohydrate) and a vitamin blend to their composition (see examples).

The compositions as set forth in Ringe et al. are seen to anticipate the compositions as set forth in claims 24-27, 29-31, and 34-36 of the instant application.

Applicant's arguments filed August 28, 2004 have been fully considered but they are not persuasive. Applicants argue that their invention has a different physical structure and omits several elements of Ringe. Applicants additionally argue that they do not require the same elements, ratios, and restrictions that are necessary for Ringe. However, it is noted, that all of the claimed elements in the instant applicants claims 24-27, 29-31, and 34-36 are necessarily contained in Ringe, as such, Ringe has all of the elements required by the instant application and therefor anticipates claims 24-27, 29-31, and 34-36. Applicants should point out that which they are claiming which is not contained in Ringe to overcome the instant rejection. Applicants argue that Ringe requires at least 8 ingredients. However, the instant claims use open claim language (i.e., "comprising"), and thus can have any other agents included therein and only require oat, psyllium, and guar, which Ringe clearly has, and thus properly anticipates said claims. Applicant argues that their compositions have a new use, and thus should be patentable over Ringe, however, the intended use of a composition has no patentable import on a composition which can otherwise stand alone, and as such, the compositions as claimed are anticipated by the compositions of Ringe. Applicants argue that their composition is unobvious over Ringe under section 103. It is noted that no 103 rejections are pending, as these rejections fall under 35 U.S.C.

Art Unit: 1623

102, and are anticipatory references not obviousness references. Applicants argue that their invention produces unexpected results. It is noted that evidence of unexpected results does not overcome a 102 rejection, as the prior art's compositions must have necessarily performed the same results, as it is the same composition, thus has the same properties, and thus would produce the same results. Applicants argue that their compositions do not require vitamins, however, these limitations are not in the claims, and thus applicant is arguing limitations which are not in the claims. Applicants argue that their invention is novel as it omits required elements of Ringe. However, as set forth supra, applicants use open claim language and thus applicants claims do not delimit anything from being contained therein and can include other agents. Applicants arguing commercial success is not convincing regarding a 102 rejection, as commercial success is used to overcome a 103 rejection. See MPEP 716.01(a) below (**emphasis added**):

716.01(a) [R-2] Objective Evidence of Nonobviousness

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHEN TIMELY PRESENT

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103.

It is noted that all of applicants arguments drawn to being "unobvious" are not convincing, as the rejections of record are not obvious-type rejections, but are anticipatory rejections, as Ringe has all of the elements required by the instant applications claims.

The rejection of claims 37 and 40-41 under 35 U.S.C. 102(b) as being anticipated by Ringe et al. (US Patent 5,026,689) is maintained for reasons of record. Newly added claims 65, 67-70, and 72-74 are rejected for the same reasons.

Art Unit: 1623

Claim 37 is drawn to a method of improving the health of a mammal comprising orally administering a composition as set forth supra wherein the health benefit is optionally treating abnormal serum cholesterol. Claim 40 provides that additional fibers are added to the composition and claim 41 provides that various vitamins, etc., are added to the composition. Claim 65 is drawn to a method of improving the cardiovascular health of a human by administering a composition as set forth above. Claim 67 provides the composition is optionally a solid and a liquid is additionally administered. Claim 68 provides an additional fiber is added. Claim 69 provides various vitamins, etc., are added to the composition. Claim 70 is drawn to reducing toxin absorption by administering the composition above. Claim 72 provides the composition is optionally a solid and a liquid is additionally administered. Claim 73 provides an additional fiber is added. Claim 74 provides various vitamins, etc., are added to the composition.

Ringe et al. disclose various oat, psyllium, and guar compositions (together with additional fibers and vitamins) as set forth supra. Ringe et al. additionally disclose that their composition is effective in lowering blood serum cholesterol (column 8, lines 39-40).

The compositions and methods of treatment as taught by Ringe et al. are seen to anticipate the compositions and methods of treatment as claimed in the instant application.

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that the Ringe et al. composition is different than the instantly claimed composition, and thus the methods of use must be different. However, as set forth supra, the compositions above are anticipated by Ringe, and thus they are not patentably distinct over Ringe et al. It is additionally noted that applicant's methods as claimed must have inherently been performed by Ringe et al., as the same composition is being administered to the same population in the same

Art Unit: 1623

amounts, and thus would indeed produce the same results. It is noted that if Ringe et al., having taken the manipulative steps described therein, had attempted to measure for the results as described in the instant application, Ringe would have uncovered those results, as they are directly correlative to the method as practiced by Ringe. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using the prior art's compositions, as the prior arts method would have inherently performed the method as instantly claimed. See *Ex Parte Novitski*, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle. Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. *EMI v. Cypress Semiconductor*, 2001 US Fed. Cir. Ct. of App.

Allowable Subject Matter

Claim 64 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art is not seen to teach or fairly suggest compositions comprising at least 7 grams of fiber selected from the group consisting of oat, guar, and psyllium, and a flavoring agent, which is admixed with a liquid to create an 8oz beverage. The prior art teaches solid compositions, and

Art Unit: 1623

one of skill in the art would not find it obvious to form a beverage out of said fibers due to their normal gelling properties in liquids.

Claims 38, 32-33, 66, and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
May 2, 2005



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623